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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,626	01/10/2005	Manuel Rosa-Calatrava	017753-200	9366

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,626	ROSA-CALATRAVA ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 1/10/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. As indicated on the Form PCT/DO/EO/903 of 6/26/06, the Office had received only the information disclosure statement. The absence on this form that the copies of the documents had also been received indicates that the documents themselves had not been received. Consequently, the information disclosure statement is incomplete. See. Since the submission appears to be *bona fide*, applicant is given within the time period set for response to this Office action to rectify the above mentioned omissions or corrections in the information disclosure statement. Failure to timely comply will result in the above mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See MPEP 1893.03(g) and 37 CFR 1.97(i).

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a modified adenoviral fiber protein monomer or trimer comprising same, wherein the modification(s) affect interaction of the fiber trimer with a glycosaminoglycan or sialic acid-containing receptor.

Group II, claim(s) 19, drawn to a DNA encoding a modified fiber protein of group I.

Group III, claim(s) 20-34, 40-41, drawn to an adenoviral particle comprising a trimer of group I.

Group IV, claim(s) 35-39, 42-43, drawn to a method for preparing the adenoviral particle of Group III.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature shared by groups I-IV is a fiber protein in which one or more amino acid residues involved in binding glycosaminoglycan or sialic acid-containing receptor is altered. This shared technical feature is not a special technical feature, since such modified fiber proteins, and adenovirus containing them, were known in the prior art. For example, Wickham et al. (US 5,770,442 at col. 12, Example 2) describes a human Ad5 (hAd5) fiber in which the entire knob domain had been substituted with the knob of hAd3. Thus all of the residues in the AB, CD, and DG loops and I sheet involved in binding glycosaminoglycan or sialic acid-containing receptor by the hAd5 fiber and residues involved in CAR binding have been modified. Liessner et al. (Gene Ther. 8: 49-57, Jan. 2001) describes adenoviral fiber proteins of human Ad5 with the T404G or A406K substitution (claim 7), and fiber proteins with other substitutions that affect CAR binding. Legrand et al., WO 98/44121, describes hAd5 fiber proteins in which residues 445-462 have been substituted with the corresponding residues of hAd3, which includes the V452K substitution (claim 7); see col. 6, lines 6-19, of US 6,569,677, which is the US national phase of Legrand and is provided as a translation.

This application contains claims directed to more than one species of the generic invention of Group I. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are an hAd5 fiber having only one of the single substitutions listed in claim 7, having a specific combination of the substitutions listed in claim 7, or only one of the combinations of substitutions listed in claim 8; or an hAd2 fiber having only one if the substitutions listed in claim 9 or a specific combination of the substitutions listed in claim 9. Applicant should identify the parent fiber protein, i.e. Ad5 fiber or Ad2 fiber, and one specific substitution or combination of substitutions in the Ad5 fiber or one specific residue or one specific combination of residues being substituted in the Ad2 fiber.

In addition to the substitutions indicated above, the species does not have an additional mutation that affects binding to CAR; the species is an Ad2 fiber has an additional generic mutation that affects CAR binding; or the species is an Ad5 fiber that has one additional mutation at one of the amino acids listed in claim 12 or at a specific combination of the amino acids listed in claim 12.

Claims 1-5 and 15-18 are generic. Claim 6 corresponds to the species of Ad5 fibers only. Claims 10 and 11 correspond only to species that have an additional mutation affecting CAR binding, and claims 12-14 correspond only to species that are hAd5 fibers with only one mutation or a specific combination of mutations that affect CAR binding in addition to the mutation(s) affecting binding to a glycosaminoglycan or sialic acid-containing receptor. Examples of a single species are 1) an hAd5 fiber with a K506Q and H508K, and no mutation

affecting CAR binding; 2) an hAd5 fiber with A406K, L506Q, and H508K mutations and a mutations of L485 and Y491; 3) an hAd2 fiber with a mutation at Q508 and no mutation affecting CAR binding; or 4) an hAd2 fiber with mutations at D406 and T556 and a mutation affecting CAR binding.

Should Applicant elect one of groups II-IV and add claims corresponding to one or more of claims 6-14, then Applicant should elect a single species of fiber protein as indicated above (where applicable). Otherwise, a supplemental restriction requirement may be necessary.

This application contains claims directed to more than one species of the generic invention of Group III. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are a particle that does not further comprise a heterologous ligand or an particle that comprises a heterologous ligand. If the species comprises a heterologous ligand, then the species are those wherein the ligand is:

1) a) chemically or immunologically coupled or

b) genetically coupled;

to the:

2) a) penton;

b) hexon;

c) fiber;

d) protein IX;

e) protein VI ; or

f) protein IIIa.

If the species has a heterologous ligand that is genetically coupled to the fiber, then the species has the ligand inserted either at the C-terminus or into the HI-loop. Examples of species are: a particle that does not comprise a heterologous ligand; a particle with a heterologous ligand chemically or immunologically coupled to the hexon; a particle with a heterologous ligand genetically inserted into protein IX; and a particle with a heterologous ligand genetically inserted into the HI loop of the fiber.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons set forth above because modifications in adenoviral fiber proteins that would affect binding to glycosaminoglycan or sialic acid-containing receptor alone or also binding to CAR were known in the art, and thus the generic concept tying these species together is not a special technical feature. With respect to the particles (group III), the inclusion of such fibers into an adenoviral particle was known in the art, and so this is not a special technical feature. Also, the attachment of a heterologous ligand to an adenoviral particle in which the fiber has been mutated to reduce or eliminate binding to a native receptor was also known in the art, for example, see Legrand et al., WO 98/44121, which discloses genetically inserting a ligand at the C-terminus of the fiber or into the hexon or penton; see col. 7 of US 6,569,677, which is the US national phase of Legrand and is provided as a translation. Consequently, the generic concept linking these species is not a special technical feature.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633